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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

[30Day-13-0040]

Agency Forms Undergoing Paperwork Reduction Act Review

The Agency for Toxic Substances and Disease Registry (ATSDR) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Generic Clearance of ATSDR Exposure Investigations (EI) [OMB Control No: 0923-0040, Expiration Date 11/30/2012] - Reinstatement with Change - Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) requests a change to a three-year "generic clearance". The title has changed since publication of the 60-day Federal Register Notice to read - *Generic Clearance of ATSDR Exposure Investigations (EI)*. The goals remain the same but ATSDR believes the change will allow the Agency to carry out its public health activities in a more timely and efficient manner. The benefits to using the EI Generic Clearance

include submission of a standardized OMB review package for each EI Generic Information Collection (GenIC).

The ATSDR Division of Community Health and Investigation (DCHI) conducts public health assessments (PHAs) at sites when requested by the U.S. EPA, states, organizations, or individual petitioners. The purpose of the agency's PHA process is to find out whether people have been, are being, or may be exposed to hazardous substances and, if so whether that exposure is harmful, or potentially harmful, and should therefore be stopped or reduced. The process also serves as a mechanism through which the agency responds to specific community health concerns related to hazardous waste sites.

Exposure assessment is the hallmark of the PHA process. ATSDR scientists review environmental data to see how much contamination is at a site, where it is, and how people might come into contact with it. Generally, ATSDR does not collect its own environmental sampling data but reviews information provided by federal and state government agencies and/or their contractors, potentially responsible parties, and the public. When adequate environmental or exposure information does not exist to assess human exposures and possible related health effects, ATSDR will indicate what further environmental sampling may be needed and may collect environmental and biological samples, when appropriate.

Therefore, as part of the PHA process, the DCHI Science Support Branch (SSB) uses EIs to fill data gaps that are essential for evaluating whether communities are exposed to contaminants and whether a health hazard is present. The EI team conducts point of human-contact sampling focused on geographic areas where exposures are expected to be high. EIs may include environmental (ambient air, personal air, indoor air, dust, soil, sediment, biota, ground water,

tap water and surface water sampling) or biological sampling (blood and urine sampling), or both. Most EIs sampling events are completed over a period of days to months and are a one-time occurrence.

An EI aims to identify the most highly exposed individuals and measure their exposure. The results of the investigation are site-specific and apply only to the participants from the site. An EI is not considered a health study. The participants' results are not intended to be generalized to other populations and other communities. No participants from external comparison groups are included in the data collection. As a public service, EIs provide individual exposure information back to the participants. EIs are also used as the basis to implement appropriate public health actions that reduce exposure to communities.

Information obtained from the participants assists the team in determining if exposure has occurred or is occurring. For each EI, a data collection system will include all of the measurements and procedures that are proposed to address data gaps in biological and environmental sampling.

ATSDR collects contact information (e.g., name, address, phone number) to provide the participant with their individual results. General information, which includes height, weight, age, race, gender, etc., is also collected primarily in biological investigations to assist with results interpretation. Some of this information is investigation-specific; not all of these data are collected for every investigation.

ATSDR also collects information on other possible confounding sources of chemical(s) exposure such as medicines taken, food eaten, hobbies, jobs, etc. In addition, ATSDR asks questions on recreational

or occupational activities that could increase a participant's exposure potential. That information represents an individual's exposure history. With these data, we can assess the presence or absence of a specific exposure and estimate how long and how frequently people have had contact with the chemical(s) of interest. The responses also provide data about exposure to other sources of the chemical(s).

Participation in an EI is completely voluntary and requires participants' written consent. To assist in interpreting the sampling results, a survey questionnaire appropriate to the specific contaminant is administered to participants. Information is generally gathered in a face-to-face interview with potentially exposed participants, but could occasionally be administered by phone or mail. All information is usually collected and recorded electronically and, on occasion, hard copy forms will be used.

ATSDR uses approximately 12-20 questions about environmental exposures per investigation. This number can vary depending on the number of chemicals being investigated the route of exposure (e.g., breathing, eating, touching), and number of other sources of the chemical(s) (e.g., products used, jobs).

Typically, the number of participants in an individual EI ranges from 10 to 100. Questionnaires are generally needed in less than half of the EIs (approximately than 12 per year).

The DCHI SSB EI team and the ATSDR staff and partners in the DCHI cooperative agreement program will use the EI Generic Clearance for OMB submittals for each EI. EIs are usually nonresearch investigations, but occasionally may be classified as research. The DCHI cooperative agreement operates across ten ATSDR regions across

the nation. In 2012, ATSDR was functionally reorganized and DCHI was divided into three functional units that administer its ten regions and its cooperative agreement program: Eastern Branch, Central Branch and Western Branch. The DCHI SSB supports all three DCHI branches. It is uncertain at this time how many EIs across the states, regions, and branches will require an expedited approval at the same time.

EI participants will likely include community members that are concerned about being exposed to environmental contamination. Investigations tend to focus on the most highly exposed at the site, such as those living in proximity to the site. On occasion, small businesses may be included as EI participants.

The estimated annual burden hours are 600, which is an increase from the previously approved burden hours of 375 hours. The increase is due to the addition of EIs conducted by cooperative agreement states requiring a survey each year. There are no costs to the respondents other than their time.

EIs are performed under the authority of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), commonly known as the "Superfund" Act, as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in hours)

Exposure Investigation Participants	Chemical Exposure Questions	1,200	1	30/60
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